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RELIABILITY OF ISOKINETIC FES INDUCED KNEE EXTENSION IN SPINAL CORD INJURY

by

LAURA ANNE MAY

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of MASTER OF SCIENCE.

DEPARTMENT OF PHYSICAL THERAPY

Edmonton, Alberta

Spring, 1994

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Laura May

14512 - 26 St
Edmonton, Alberta
T5Y 1W7

Dated: April 21, 1994

UNIVERSITY OF ALBERTA

FACULTY OF GRADUATE STUDIES AND RESEARCH

The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled RELIABILITY OF ISOKINETIC FES INDUCED KNEE EXTENSION IN SPINAL CORD INJURY submitted by LAURA ANNE MAY in partial fulfillment of the requirements for the degree of MASTER OF SCIENCE.

Dr. David Magee

Dr. Robert Burnham

Dr. Thomas Martin

Dated: April 18, 1994

DEDICATION

In loving memory of my father, Gerard Schell, a devoted teacher whose knowledge and wisdom has guided me in all that I am and all that I do. I hope that I have given him reason to be proud.

ABSTRACT

The purpose of this study was to evaluate the reliability of a protocol using the KinCom isokinetic dynamometer to measure knee extension induced by functional electrical stimulation (FES) in spinal cord individuals. Fifteen subjects, aged 18 - 42, all with complete spinal cord injuries between the levels of C6 and T10 participated in the study.

Reliability was determined for maximal and submaximal contractions at two angular velocities (30° and 90°/second) for measurements taken on the same day and measurements taken within one week. A pulse frequency of 30 Hz and pulse duration of 300 microseconds was used for all subjects. To include each combination of contraction type and velocity, each subject performed four sets of five contractions.

The peak torque of the best three contractions for each set was used in the statistical analysis. The intraclass correlation coefficient (ICC) used to determine reliability ranged from 0.89 - 0.98, and the statistical significance was determined by the calculation of the 95% confidence limits. The standard error of measurement (SEM) ranged from 2.8 - 5.4 Nm. A Z-test of significance indicated that there was no statistically significant difference between the correlation coefficients.

This data suggests that the protocol used in this study to measure isokinetic FES induced knee extension in individuals with spinal cord injury was reliable.

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LIST OF ABBREVIATIONS

SCI	Spinal Cord Injury
FES	Functional Electrical Stimulation
Nm	Newton meters
MVC	Maximal Voluntary Contraction
Hz	Hertz
EMG	Electomyography
CT	Computed Tomography
QMP	Quadriceps Muscle Performance
mA	milliamp
ft-lb	foot pound
ICC	Intraclass Correlation Coefficient
CVA	Cerebrovascular Accident
cm	centimeters
SEM	Standard Error of Measurement

I. THE PROBLEM

A. INTRODUCTION

Varied forms of electrical stimulation have been used to produce contractions of upper motor neuron paralysed skeletal muscle in patients with Spinal Cord Injury (SCI). Functional electrical stimulation (FES) has been used clinically and in research to assist functional movement, improve cardiovascular fitness and prevent secondary complications in spinal cord injuries (Yarkony et al.,1992a; 1992b). Programs to provide standing and walking through functional electrical stimulation are ongoing in many countries (Hjeltnes & Lannem,1990; Marsolais & Kobetic,1987; Turk et al.,1980). Muscle strength and endurance are parameters that are crucial to the success of these programs. Peckham (1987) stated that virtually every investigator using electrical stimulation for restoration of functional movement incorporates a muscle strengthening program into the clinical protocol.

Much of the research has focused on the evaluation and conditioning of the quadriceps muscles, since they represent the smallest number of muscles that must be stimulated to achieve stance (Yarkony et al.,1992a). Improved strength and endurance have been reported using varied forms of FES induced exercise (Hjeltnes & Lannem,1990; Bremner et

al.,1992; Rabischong & Ohanna,1992; Rodgers et al.,1991; Gruner et al.,1983; Ragnarsson et al.,1988). The subjects involved in the FES research have upper motor neuron paralysis which is amenable, as will be discussed later, to the electrical stimulation techniques most often described in the literature (Yarkony et al.,1992a; Phillips,1991).

Generally, there are two types of control for the application of FES. Closed-loop control involves the use of sensors to monitor force or position of the limb and the current output of the stimulation is continually modulated as in the studies of Ezenwa et al.(1991), Pacy et al.(1987) and Fournier et al.(1984). Open-loop control uses a predetermined stimulation pattern and does not involve feedback for adaptation of the stimulation. This type of stimulation is typically used in the clinic, although this application has been utilized in some research studies (Marsolais & Kobetic,1987; Stein et al.,1992; Bremner et al.,1992). Methods for the delivery of electrical stimulation can involve external systems, percutaneous systems or implanted systems (Yarkony et al.,1992a).

Functional Electrical Stimulation is viewed as an emerging technology in the area of rehabilitation medicine. More research is needed to solve the existing problems associated with electrical stimulation and to substantiate the potential benefits (Yarkony et al.,1992a; Glaser,1986).

A. STATEMENT OF THE PROBLEM

Clinicians, researchers and subjects must collaborate closely to define reasonable clinical objectives, identify the approach to specific problems and implement solutions for the use of FES (Peckham,1987). Strength requirements and precise training protocols to achieve the strength necessary for the successful application of FES for functional mobility of the spinal cord injured individual has yet to be determined. One of the limitations in establishing strength requirements is the limited use of reliable measuring devices to measure torque produced in paralysed muscle.

The evaluation of strength as described in the literature to date, involved isometric tests (Bremner et al.,1992; Rabischong & Ohanna,1992; Binder-Macleod & Barker,1991) or tests of clinical observation (Rodgers et al.,1991; Gruner et al.,1983; Ragnarsson et al.,1988). These studies may not be the most appropriate, given that the type of exercise performed often involves movement through a defined range of motion. Often, the measurement apparatus has been specifically designed for use in the research laboratory (Rabischong & Ohanna,1992; Stein et al.,1992; Bajd et al.,1990; Levy et al.,1990). There are few reports regarding the reliability of the assessment tools used and often, statistical analysis is not included. Only four of the reviewed studies in which isometric testing was used, gave reliability coefficients for the force measurements.

All studies involved able bodied subjects and therefore, the reliability results may not be directly applicable to SCI individuals (McDonnell et al.,1987; Binder-Macleod & Barker,1991; Binder-Macleod & Guerin, 1990; Binder-Macleod & McDermond,1992).

An isokinetic testing device could allow measurement of muscle forces produced through a range of motion at a velocity that is specific to the activities performed. An isokinetic device such as the KinCom (Chattecx Corp.) is commercially available and can objectively evaluate the strength parameters of peak torque and average torque. Edwards and Marsolais (1987) evaluated isokinetic muscle force data in three complete paraplegics using an angular velocity of 60^0/sec as slower speeds were less specific to the angular velocity of walking. However, the test velocity cannot be related directly to the velocity of walking as a sitting position is used during testing. Hjeltnes and Lannem (1990) trained and tested four complete paraplegics using angular velocities of 30^0 and 90^0/second.

Not only is isokinetic testing more specific to the activities performed as there is movement through a range of motion, but there is also some indirect evidence that isokinetic assessment may be safer than isometric testing of FES induced contractions in the spinal cord injured individual. Hjeltnes and Lannem (1990) demonstrated that FES induced peak torque measurements were greater during

isometric testing than isokinetic testing at 90^0/sec for all paraplegic subjects. This relationship is consistant with that seen in normal subjects (Thorstensson et al.,1976). Fournier et al.(1984) assessed the maximum FES induced isometric strength of the quadriceps in five paraplegics. It was reported that one subject suffered a transverse patellar fracture during the first stimulation session. Ragnarsson (1988) reported that there were no adverse effects experienced by any of the SCI subjects who participated in training programs of isotonic and isometric exercise. In voluntary contractions, eccentric activity produces greater force than both isometric or concentric (isotonic or isokinetic) activity. There are no reports in the literature comparing FES induced eccentric and concentric forces.

Presently, there are no reliability or validity studies of the KinCom as an assessment tool for strength of FES induced contractions in spinal cord injured individuals. Establishing the reliability of the KinCom as an outcome measure may assist in determining the optimal stimulation parameters for training and functional activity. Reliable measurement of FES induced force within one session may contribute to the understanding of the observations of fatigue during electrically stimulated contractions. It has been stated that the knee joint torques as measured isometrically must meet a minimum standard of 50 Newton metres (Nm) to allow standing and bipedal walking in

complete paraplegics (Bajd et al.,1989; Barr et al.,1989). No reports regarding the reliability of these torque measurements were given. If it is the intent of researchers to establish minimal force requirements as predictors of success in achieving functional goals, then it would be necessary to be confident that those measurements were reliable.

B. OBJECTIVES OF THE STUDY

The purpose of this study was to evaluate the intra-session and inter-session reliability of peak torque as measured by the KinCom during isokinetic FES induced knee extension in spinal cord injured individuals. Reliability of isokinetic FES induced knee extension was examined over two set time periods, measurements taken on the same day and measurements taken within one week. Inter-session measurements were taken at the same time of day to minimize the impact of diurnal variations (Wright,1959; Lee et al.,1974; Pearson et al.,1982). Maximal and submaximal concentric contractions were examined at two selected velocities of which the order was randomly determined. The right (R) leg was used for testing in all instances to maintain consistency.

C. SIGNIFICANCE OF THE STUDY

As FES is becoming more widely used clinically and in

research to improve torque production in paralysed muscle, it is necessary to establish safe and reliable methods to evaluate these gains. It is also hoped that with the determination of the reliability of strength measurement, further research can accurately establish strength requirements for functional activities such as standing and walking and determine precise protocols for the training to attain these levels.

D. RESEARCH HYPOTHESIS

The research hypothesis was that the peak torque as measured by the KinCom during FES induced knee extension in spinal cord injured subjects would be reliable:

a) for measurements taken on the same day (intra-session)
b) for measurements taken within one week (inter-session)
c) for maximal and submaximal concentric contractions
d) for two set angular velocities, 30^0 and 90^0/second (rationale discussed in Methods)

E. OPERATIONAL DEFINITIONS

1) **KinCom Isokinetic Dynamometer-** a hydraulically driven, microcomputer controlled device designed to measure torque and work during eccentric and concentric loading (Tredinnick & Duncan,1988).

2) **Isokinetic-** a situation in which muscles contract and generate force as the body segment distal to the joint axis moves at a constant velocity.

3) **Torque-** product of the distance of the lever arm times the force component perpendicular to the lever arm. Units are measured in Newton metres (Nm) (Gould & Davis,1985,p.75).

4) **Concentric contraction-** a situation in which the muscle shortens as it develops tension and overcomes a resistance (McArdle, Katch & Katch,1981,p.291).

5) **Eccentric contraction-** a situation in which the external resistance overcomes the actively contracting muscle and the muscle lengthens while developing tension (McArdle, Katch & Katch,1981,p.291).

6) **Strength-** For the purposes of this study, strength referred to the production of force in paralysed muscle as generated by functional electrical stimulation.

7) **Functional Electrical Stimulation-** the generation of a contraction of a muscle by the initiation of action potentials in intramuscular nerve branches by controlled intensity, form and frequency of pulses from an artificial stimulus.
Physiologically mediated muscle contraction is

initiated by the central nervous system and involves asynchronous excitation of the motor units with ascending recruitment order from small to large motoneurons. In peripherally applied electrical stimulation, used in this study, only a limited number of motor units are continually excited and because the larger axons have a lower threshold of excitability, the recruitment order of motoneurons occurs from large to small (Cybulski et al.,1984; Benton et al.,1981).

8) **Reliability-** consistency of a measure when all conditions are thought to be held constant (Rothstein,1985,p.10).

9) **Angular Velocity-** the speed at which the limb will move through a predetermined range of motion.

F. DELIMITATIONS

1) This study was limited to individuals who met the inclusion criteria.

2) The FES induced knee extension strength determination was limited to constant velocity movement performed at two preselected speeds.

3) The muscle force produced was limited to preselected stimulation parameters.

G. LIMITATIONS

1) The reliability of the KinCom unit was limited to the calibration accuracy of the dynamometer and the recorder and the accuracy of the stabilization of the subjects by the researcher. To ensure accuracy of the KinCom, a system calibration check as outlined in the manual (Appendix A), was performed by a qualified service technician prior to commencement of the study.

2) The consistency of the induced muscle contraction was limited to the accuracy of the output of the stimulator and the variable tissue impedance of the subjects. To ensure accuracy, the frequency, pulse width and current output at each setting were measured using a digital storage oscilloscope (Phillips, PM 3375) prior to the testing of each subject.

3) A potential limitation was the variability of the levels of spasticity and prescribed medications of the subjects. The pre-test questionnaire (Appendix B) was used to record the medications and dosages along with other information relating to the selection criteria (see Methods).

H. ETHICAL CONSIDERATIONS

Prior to commencement of the study, the project

received approval from the Ethics Committee at the Glenrose Rehabilitation Hospital and the SPERRC Committee of the Department of Physical Therapy, Faculty of Rehabilitation Medicine, University of Alberta. All testing took place at the Glenrose Rehabilitation Hospital during times when medical staff, familiar with the safety protocols, were available. A physician was present at the first test session. All subjects signed a consent form (Appendix C) prior to any testing and it was ensured that they were aware that participation was voluntary, that they could withdraw at any time without prejudice and that all information resulting from the study was kept confidential.

There are benefits to clinicians and researchers to establish the reliability of a tool to measure FES induced torque production. However, there are certain risks involved with FES induced muscle contractions. There was the possibility that the subject could display symptoms of autonomic dysreflexia which is most often evident by the symptom of extremely high systolic blood pressure (Glaser,1986). For the definition of autonomic dysreflexia, description of the symptoms, and the safety protocol for its management, see Appendix D. At present, there are varying reports in the literature regarding episodes of autonomic dysreflexia during FES. Recent studies (Ashley et al.,1993; Arnold et al.,1992; Gruner et al.,1983) have described instances in which subjects exhibited a marked increase in

blood pressure during FES exercises, a response suggestive of autonomic dysreflexia. In contrast, Ragnarsson (1988) and Hooker et al.(1990) stated that there were no episodes of autonomic dysreflexia during FES induced exercise. In order to detect a dysreflexic reaction, the research assistant monitored blood pressure automatically during all testing using a sphygmomanometer, Sunbeam, model 7650.

There was also the potential for lower extremity fractures during FES induced contractions. Among the articles reviewed, only Fournier et al. (1984) reported a single case of a lower extremity fracture (fractured patella) as a result of FES induced muscle contractions. A retrospective study of 578 spinal cord injured patients found the occurrence of documented lower extremity fractures was only four percent (Ragnarsson & Sell,1981). The most common cause was a fall and there were no reports of FES induced fractures. The potential for fracture is of concern in this study as the subjects were up to 10 years post-injury and may be more susceptible to fracture as there is decreased bone density due to osteoporosis (Ragnarsson & Sell,1981). As a precaution, all subjects were required to have a radiological examination of the right leg to rule out any recent or existing fracture and define the level of osteoporosis as mild, moderate or severe (Phillips,1991). Only subjects that had a level of osteoporosis defined as mild or moderate participated in the study. The existance of

a fracture or a severe level of osteoporosis could put subjects at greater risk of fracture during FES induced muscle contractions. In previous use of FES clinically and in research, this investigator had no occurrence of such an injury. As an additional safety precaution, maximal force limits were set on the KinCom. In the event of fracture, a safety protocol had been determined but was not needed (Appendix D).

The use of surface applied electricity to stimulate muscle always carries with it the risk of electrical burns. Balmaseda et al. (1987) described two case reports of electrical burns in spinal cord injured subjects during FES and discussed methods to minimize their occurrence. For this study as described in the methods, each subject's skin was prepared, larger electrodes were used, the electrodes were self adhesive to ensure uniform contact with the skin, and there was adequate conductive material on the electrodes. After all test sessions, each subject's skin was checked for possible skin irritation.

II. LITERATURE REVIEW

The literature review is arranged into four main segments and addresses the following topics:

1) Functional Electrical Stimulation
2) FES Induced Strength
3) Outcome Measures
4) Reliability and Validity

A. FUNCTIONAL ELECTRICAL STIMULATION

Functional Electrical Stimulation (FES) represents an artificial means of activating muscle which bypasses the processes associated with voluntary muscle contraction (Trimble & Enoka,1991). The excitability of nerve and muscle tissue provides the basis for the therapeutic use of FES (Benton et al.,1981).

Physiological activity of voluntary contractions differ mainly in recruitment order and the asynchrony of excitement of separate motor units (Benton et al.,1981). During voluntary contractions, the motor unit recruitment order progresses in an ascending order as a function of the size of the motoneurons (Henneman & Mendell,1981). A stimulus must be of adequate magnitude and sufficient duration to equal or exceed the threshold of excitation for the tissue. In peripherally applied electrical stimulation, the first

units to fire are those that are most excitable (Benton et al.,1981). The larger fibres are innervated by larger axons and have a lower threshold of excitability, so it would seem reasonable to expect that larger motor units would be recruited first during FES (Knaflitz et al.,1990).

Trimble and Enoka (1991) evaluated evoked H-reflexes and M-responses of the quadriceps muscle in 22 able-bodied volunteers using electromyography (EMG). The resultant decrease in time to peak force was interpreted as the activation of fast contracting motor units and evidence that percutaneous electrical stimulation as compared to volitional activity could alter the recruitment order of motor units. In contrast, Knaflitz et al. (1990) evaluated motor unit recruitment by measuring muscle fibre conduction velocity of myoelectric signals during surface electrical stimulation of the tibialis anterior muscle in 22 able-bodied subjects. In 72% of the experiments, the recruitment order was indicated to be similar to that of voluntary contractions. The results indicated that the geometric location and orientation of the nerve fibres as well as the diameter of the motorneuron branches might be more important than their electrical excitability threshold in determining recruitment order.

Of particular concern are the electrical stimulation parameters of intensity, duration, frequency and waveform as well as the size and configuration of the electrodes.

Current intensity or amplitude determines the magnitude of the sensory as well as the motor response evoked by the stimulation (Benton et al.,1981). In adjusting amplitude to achieve a desired motor response, care should be taken to ensure the stimulation is within the subjects sensory tolerance.

Pulse duration or width affects the current intensity in that as pulse duration decreases, the charge of each pulse decreases and thus the intensity to evoke a particular motor response must be increased (Benton et al.,1981). It is generally accepted that for a pulse duration of 100 to 1000 microseconds, the corresponding intensity triggers the largest non-painful force of contraction (Hainaut & Duchateau,1992). Physiological rationale and subjective reports of comfort support pulse durations in the order of 300 microseconds for clinical treatment (Benton et al.,1981).

Pulse duration rise time can affect the comfort of stimulation (Benton et al.,1981). The rise time should be as short as possible in order to avoid the membrane accommodation phenomenon, a process involving the gradual elevation of the threshold of excitation in the presence of a slowly increasing stimulus (Hainaut & Duchateau,1992; Benton et al.,1981). For patients with severe spasticity, short rise times may evoke a quick stretch of the spastic muscle or a flexor withdrawal and this possible reaction

must be taken into consideration when selecting parameters.

The stimulus frequency or pulse repetition rate affects the quality of the muscle contraction as well as the rate of muscle fatigue (Benton et al.,1981; Binder-Macleod & McDermond,1992). A frequency sufficient to cause tetanization is desirable as tension developed by a muscle in tetanus will be greater (Benton et al.,1981). Generally, the maximal FES induced force is similar to or less than the maximal voluntary contraction (MVC) (Hainaut & Duchateau,1992). Frequencies between 30 and 35 Hz are usually sufficient to achieve a tetanized contraction in most muscles. In fast twitch muscle, tetanic fusion frequency is reached at higher stimulation frequencies than in slow twitch muscles (Bigland-Ritchie et al.,1983).

The most efficient frequencies for producing maximal force appear to be in the range from 50 - 120 Hz (Hainaut & Duchateau,1992). Binder-Macleod and McDermond (1992) found that the lowest frequency needed to produce a contraction greater than 90% of the maximal voluntary contraction of the 20 able-bodied subjects was approximately 55 Hz. Cox et al. (1986) found that all 30 able-bodied subjects were able to produce peak contractions induced by electrical stimulation using a frequency of 100 Hz. The contractions averaged 85 % of MVC.

Although higher frequencies produce greater force outputs, the main disadvantage is the rapid rate of fatigue

that is observed when using high stimulation frequencies. Jones et al. (1979) demonstrated that for stimulation of the adductor pollicis muscle in able-bodied subjects, the rate of force loss during a frequency of 80 Hz was greater than at 20 Hz. The force generated at 20 Hz was about 70% of MVC compared to 100% MVC at 80 Hz. However, force decreased to 80% of initial value in the first 12 seconds for 80 Hz, whereas at 20 Hz force was maintained for 20 to 30 seconds and then gradually declined.

There is also evidence to suggest the relationship between force and frequency is affected by the fatigue of the muscle. Binder-Macleod and McDermond (1992) evaluated the force-frequency relationship by comparing force values produced at varying levels of frequency, both before and after fatigue of the quadriceps muscles. It was demonstrated that there was a selective loss of force at the lower frequencies and that at high frequencies (>60 Hz), near maximum force was maintained. Results suggested that the most appropriate stimulation frequency to use depended on the percentage of tetanic force desired and the fatigue state of the muscle. In contrast, Jones et al. (1979) and Binder-Macleod and Guerin (1990), found that reduction of stimulation frequency in a fatigued muscle resulted in an increased force. The primary difference between these controversial studies is that one was examining force produced by a certain frequency after fatigue was induced

whereas the others looked at the force-frequency relationship as fatigue was occurring.

Alterations in fatigability have been examined in spinal cord injured individuals using varying exercise protocols. Stein et al. (1992) found that the fatigability of the tibialis anterior muscle in five SCI subjects was significantly less after a six week period of stimulation (8 hours per day at a frequency of 20 Hz). The rate of fatigue was similar to that of matched non-disabled controls who did not undergo stimulation. Peckham et al. (1976) evaluated a 30 week stimulation program of the finger flexors in 12 quadriplegics using a stimulation frequency of 10 Hz. In 10 of the subjects, force and fatigue resistance improved after participation in the program.

Fatigue responses have been measured under varying conditions of electrical stimulation. Edwards and Marsolais (1987) examined the fatigue response during isokinetic FES induced knee extension in 3 complete paraplegics. A stimulation frequency of 25 Hz was used. The rate of muscle fatigue as determined by the time to 50% of initial force ranged from 20 seconds to two minutes. Pournezam et al. (1988) evaluated the rate of muscle fatigue comparing the use of continuous and sequential stimulation with a frequency of 20 Hz. The rate of fatigue, time to 50% of initial contraction as measured isometrically, was significantly different. The sequential stimulation was most

effective in delaying muscle fatigue.

Susak et al. (1986) and Turk et al. (1980) examined fatigue responses of the quadriceps and plantar flexors using different stimulation parameters. The lowest level of fatigue was found at low stimulation frequencies, the optimal parameters were determined to be a frequency of 20 Hz combined with a pulse duration of 300 microseconds. Although fatigue responses are variable and can be affected by factors such as contraction type and mode of stimulation, it appears consistent that lower frequency levels are preferable in the SCI population.

The stimulation "on" time and the rest period are also related to fatigue. An on:off ratio of one to three seconds is generally suitable for patients without producing functional fatigue during a thirty minute program (Benton et al.,1981). Cox et al. (1986) found that in non-disabled subjects, a 50 second rest interval between isometric contractions of the quadriceps produced the least torque decrement. Rest between contractions can also have an effect on the reliability of measurements. Stratford et al. (1990) examined the effect of a rest and no rest protocol on the reliability of isokinetic knee flexion and extension torque. Higher reliability coefficients were obtained for the rest protocol and the standard error of measurement was found to be less.

Electrodes play a major role in determining the

effectiveness of electrical stimulation. Of particular importance are the electrode site, size and orientation. McNeal and Baker (1988) found two regions of excitability for the quadriceps muscles: a localized region over the femoral nerve inferior to the inguinal ligament and a much broader region near the midpoints of the rectus femoris and vastus lateralis. They also found that the muscles were not affected by electrode size and that biphasic waveforms produced greater forces than monophasic waveforms and the results were more predictable.

Muscle motor points appear to be the most preferred site for electrode placement (Hainaut & Duchateau,1992; Brooks et al.,1990). Ferguson et al. (1989) showed that there were no significant differences in torque output of the quadriceps muscles when comparing electrode placement over the motor points of the vastus medialis, vastus lateralis or rectus femoris.

The orientation of the electrodes is of importance. Muscle conductivity is greater in the longitudinal direction (Benton et al.,1981) and it was shown by Brooks et al. (1990) that the longitudinal electrode placement produced more torque than transverse placement. The electrodes were positioned on each subject based on measurement from the anterior superior iliac spine and the superior border of the patella. Therefore, the site of placement remained the same, only the electrode orientation changed.

As there are so many variables to consider in using FES, it is difficult to determine reliability. Of the articles reviewed, there were no specific examinations of reliability of the electrical stimulation. Hultman and Sjoholm (1983) noted that EMG responses paralleled isometric force measurements of the quadriceps during continuous stimulation. In a study of the effects of submotor neuromuscular stimulation on motor unit recruitment order, Trimble and Enoka (1991) reported good reliability coefficients (0.90 to 0.99) for EMG responses measured. The consistent EMG response suggests that the current delivered to the peripheral nerve of each test muscle remained relatively constant during the stimulation.

It is difficult to analyze the efficacy of FES as used in studies of spinal cord injured and non-disabled subjects due to the diversity of protocols and the lack of details reported. The evaluation of FES in terms of force measurement, fatigue, fibre recruitment and stimulation parameters is far from conclusive and further research is necessary to understand underlying neurophysiological mechanisms.

B. FES INDUCED STRENGTH

Strengthening of paralysed muscle with FES has been demonstrated in numerous studies utilizing varying exercise protocols and stimulation parameters. Ragnarsson et

al.(1988) described a two phase training program of isotonic knee extension followed by bicycle ergometry. Phase I consisted of four weeks of quadriceps training three times per week delivered via three surface electrodes. Each subject performed 45 lifts if able, using an on:off ratio of 8:14 seconds. The stimulation parameters for this phase of training were not described. The second phase involved 12 weeks of three sessions per week of bicycle ergometry utilizing a six channel closed loop system for sequential stimulation. The frequency was 60 Hz with a pulse duration of 350 microseconds and an amplitude determined by the systems microprocessor. All nineteen subjects, 7 paraplegics and 12 quadriplegics, with clinically complete motor and sensory lesions, demonstrated improved strength as evident by increased resistance tolerated. Although it was reported that there were significant increases in strength and endurance, there was no statistical analysis presented except for the physiological measurements that were taken.

Bremner et al. (1992) also utilized a two phase exercise protocol to examine the effects of stimulation induced exercise. Four subjects with incomplete spinal cord injuries and two subjects with complete spinal cord injuries participated. The strengthening phase involved 12 weeks of stimulation to the quadriceps and hamstrings using an 8 second on, 10 second off duty cycle. There was no mention of the use of an external load. It was not stated whether the

stimulation was simultaneous or alternating and the number of sessions per week was not reported. The second phase commenced two weeks after completion of the first phase and likewise lasted 12 weeks. This cycling program was conducted three times per week for 20 minutes per day. Although exercise tolerance improved as determined by progressive increase in exercise time, cycling rate and exercise load, the isometric strength measures did not support these findings. Only one of the subjects demonstrated an increase in quadriceps strength. Measurement error was cited as the reason for the poor results.

Rodgers et al.(1991) tested the musculoskeletal responses of a newly designed knee extension training system which was originally described by Ezenwa et al.(1991). The system allowed controlled concentric and eccentric contractions with progressive external loads. The closed loop system used adaptive control methods to adjust FES current output to the quadriceps muscle to maintain performance as the muscles fatigued. The stimulation parameters included a frequency of 35 Hz and a pulse duration of 300 microseconds. Each subject trained for a total of 36 sessions (approximately three times per week for 12 weeks) using a progressive intensity protocol as determined by the external load applied. The protocol was adequately described to allow for duplication. The quadriceps muscles performance, number of knee extensions

times the total load, was calculated after the training period. All 12 subjects (4 paraplegics, 8 quadriplegics) demonstrated significant improvement as evidenced by the ability to increase the load lifted. Four subjects exhibited a ceiling effect as imposed by the safety restrictions and thus, the recorded change of their quadriceps muscle performance was likely lower than their true capability.

Gruner et al.(1983) utilized a closed loop control system which involved sequential surface stimulation. The system allowed gradual increasing and decreasing amplitude adjustments as the leg extended and then returned to the rest position. A frequency of 30 Hz and a pulse frequency of 200 microseconds were used. Six subjects with complete upper motor neuron lesions (2 paraplegics, 4 quadriplegics) participated in the isotonic exercise program which involved strength and endurance components. After the exercise sessions of one and a half hours duration per week for nine weeks, all subjects showed improved strength by the ability to increase the load lifted. There was no statistical analysis.

Barr et al. (1989) used two different stimulators to evaluate muscle power and spasticity in 19 clinically complete spinal cord injured individuals. The protocol involved 12 weeks of progressive isometric and isotonic exercise of the quadriceps and gluteal muscles. Although the treatment length of each session was mentioned, it was

unclear how many sessions per week were performed. Only five of the subjects achieved a gain in muscle power as measured isometrically on the KinCom, and fulfilled the criteria set to be able to stand.

Isokinetic training on the Cybex (Lumex Inc.) was performed by four paraplegics prior to gait training in a study by Hjeltnes and Lannem (1990). The length of the training program was unclear. Peak torque and average torque were measured isometrically and isokinetically at angular velocities from 0^{o} to 240^{o}/second. Fatigue measurements were taken at 30^{o} and 90^{o}/second. Quantitative values for strength improvements were not given for all subjects at all angular velocities. Changes in peak isometric and isokinetic (90^{o}/sec) knee extension torque were represented graphically. It was evident that all subjects showed improvement and that isometric measurement yielded greater torques than isokinetic measurements. It was also reported that all subjects were able to stand and walk using FES at the completion of the training.

Rabischong and Ohanna (1992) compared the strength of paraplegics who underwent two months of FES knee extension training with able-bodied individuals and paraplegics who were untrained. The quadriceps muscles were trained isometrically at 30 degrees of flexion, half an hour per day for two months. The ratio of on:off was 1:3 (seconds) for the first month and 1:2 (seconds) for the second month. The

stimulation parameters used included a frequency of 20 Hz and a pulse width of 300 microseconds. Isometric force measurements were taken at 90°, 70°, 60°, 45°, 25°, and 0° of knee flexion. The training was shown to have a significant effect on the quadriceps strength of the paraplegics. However, they did not demonstrate values similar to the voluntary contractions of the able-bodied individuals.

C. OUTCOME MEASURES

Various methods have been used to quantify the changes that occur in paretic muscles as a result of FES induced exercise. The extent to which these methods can be reproduced by other researchers depends on the description of the tool and its availability. For example, muscle biopsies and computed tomography (CT) have been used to evaluate the changes in muscle properties in several studies (Pacy et al.,1987; Pacy et al.,1988; Block et al.,1989). Neither of these evaluation methods would be appropriate for clinical use. For research purposes, valuable information regarding muscle bulk and fibre can be obtained. Although there is demonstration of muscle hypertrophy, the change in muscle properties cannot be equated with improved strength unless torque production is measured.

Turk et al.(1980) stated that muscle force was measured every two weeks during an isotonic exercise program by means

further description was given. A more recent study (Bajd et al.,1990) analyzed the symmetry of FES responses in the lower extremities of ten paraplegic subjects with complete SCI. A strain gauge measuring device built in their laboratory was used to evaluate FES induced isometric knee extension. Although the position of testing and the method of stimulation were well described, there was no further detail regarding the measuring device.

Other studies have based the improvement in strength and endurance on the ability to lift greater loads or perform increased repetitions. Ragnarsson et al. (1988) stated that the 19 subjects participating in a two phase exercise program showed significant increases in strength and endurance. This improvement was evidenced by an increase in the total number of knee extension lifts or by completing 45 lifts with an increased resistance. During the bicycle ergometry training phase, one third of the subjects were unable to increase the resistance but all were able to increase the length of time they could ride the ergometer.

Gruner et al. (1983) plotted the progress of six SCI subjects graphically using the load weight of each session as an indication of increased strength. Using the described protocol, approximately 24 weeks of exercise were required to reach the maximum load weight if all sessions were completed successfully. Although these methods might be utilized clinically, objective data regarding torque

measurements have not been obtained.

Using a variation of the number of lifts or level of resistance, Rodgers et al. (1991) calculated the Quadriceps Muscle Performance (QMP) for individual training sessions as the number of knee extension repetitions times the total load. The total load included the sum of the lever arm weight, the estimated lower leg weight and any externally applied load. The change in QMP was used as a muscle performance index of strength and endurance improvement.

A variety of strain gauges for measuring strength isometrically have been described in the literature. Bremner et al. (1992) utilized a strain gauge cantilever beam to measure stimulation induced quadriceps strength under isometric conditions. Three trials of stimulation were performed at three stimulation amplitudes (50, 75 and 90% of maximal output) and at two angles of extension, 30 and 60 degrees. A 10 second rest period separated each trial. It was not stated how long each contraction was held.

Rabischong and Ohanna (1992) evaluated isometric torque at six angles of knee flexion using a specially designed force transducer with strain gauges. The transducer was calibrated before each set of measurements. Maximum current output was applied for two seconds with a 30 second rest between each position assessed. It was not stated if more than one measurement was taken at each joint angle.

Isometric measurements of the quadriceps at 0^0, 30^0,

60^0 and 90^0 of knee flexion were made by means of an instrumented cantilever (Levy et al.,1990). The current amplitudes were varied in a ramp from 30 to 220 mA, within six seconds for recruitment and six seconds for recovery. Again, no statement was made as to whether there was more than one measurement for each joint angle.

Barr et al. (1989) measured isometric contractions of the quadriceps weekly using the KinCom. The measurement was taken with the knee flexed at 90 degrees. The contraction was held for four seconds followed by a four second rest. The test continued until 50 contractions had been completed or until the muscle had fatigued to 50% of the initial contraction force.

It is apparent that there is variation among all test protocols in terms of joint angles, stimulation time, rest time and number of test repetitions. Limiting the number of joint angles tested saves time but information regarding peak torque may be missed unless the test is performed at the specific angle at which peak torque occurs. Both Rabischong and Ohanna (1992) and Levy et al. (1990), found that maximum knee extension force was produced at 60 degrees of knee flexion. Similarly, Thorstensson et al. (1976) found that peak torque during isokinetic knee extension occurred in a relatively narrow range of movement, from 55^0 to 66^0 of knee flexion. Also, the peak torque occurred later in the range as the angular velocity increased. Isometric force

evaluation at 60^0 of knee flexion could represent the peak value as the angle of measurement is within the range described above. By using an isokinetic device for measurement, information regarding torque production can be continuously evaluated throughout a range of movement.

Three studies reported the use of the Cybex (Lumex Inc.) isokinetic dynamometer in evaluating FES induced muscle contractions. Marsolais and Kobetic (1987) evaluated an exercise and gait training program for eleven paraplegics utilizing multiple percutaneous intramuscular wire electrodes in the hip, knee and ankle. It was stated that torque was measured using the Cybex device although no objective data was reported. No specific information was given regarding the test protocol so it could not be determined if the measurements were isometric or isokinetic.

Hjeltnes and Lannem (1990) studied four complete paraplegics and measured isometric and isokinetic strength on the Cybex dynamometer at angular velocities from 0^0 to 240^0/second. There were no details regarding the test protocol. The data for all subjects was expressed graphically for measurements taken isometrically and isokinetically at 90^0/second.

In a study of fatigue during gait, Edwards and Marsolais (1987) evaluated isokinetic muscle torque data at an angular velocity of 60^0/second. Repetitions continued

until the torque value reached 50% of the initial value. There was a considerable range given for the three complete paraplegics who were measured. The torque generated by the subjects in this study ranged from 18 to 60 ft-lb. Although results were variable among the subjects of all three studies, it does appear that isokinetic testing is a viable option.

D. RELIABILITY AND VALIDITY

An important consideration regarding the value of an assessment tool is that reliability and validity have been established. Reliability is often assessed through the use of correlations. If paired measures correlate highly, reliability is present (Rothstein,1985). Intraclass correlations (ICC) are often used as a measure of reliability as they measure the extent to which multiple measures agree. The reliability of a measure would be considered acceptable if the ICC was greater than or equal to 0.8 (Currier,1984). Of the articles reviewed, few studies report any measure of reliability for the FES induced strength tests.

The effect of continuous (20, 40, or 80Hz) versus variable frequency (consisting of all three frequencies) on FES induced quadriceps contractions in 12 able-bodied subjects was evaluated with the KinCom in which isometric tests were performed (Binder-Macleod & Barker,1991). Intra-

test reliability was determined on four repeated measures for each subject and the intraclass correlation was determined to be 0.9146, indicating good reliability (Shrout & Fleiss,1979). The measurements were taken at the beginning of each test session which were separated by at least 24 hours.

Binder-Macleod and McDermond (1992) studied the changes in the force-fatigue relationship in 20 nondisabled subjects following voluntary and electrically elicited contractions. The force generated during all contractions was measured using the KinCom set at an angular velocity of 0^0/second to allow only isometric contractions. The reliability of this procedure was determined by calculating the intraclass correlation coefficient of the peak forces for the two sets of pre-fatigue data. At least 72 hours separated the two test sessions. An ICC value of 0.87 indicated that the reliability of the procedure was acceptable.

The rate of fatigue during intermittent FES using a protocol of progressive reduction of stimulation frequencies was compared to the rate of fatigue during constant stimulation in 12 nondisabled subjects (Binder-Macleod & Guerin,1990). The force outputs of the contractions produced by electrical stimulation were recorded using the KinCom II. Reliability was determined by comparing the average force outputs of the first contraction for each experimental session. The three test sessions were separated by at least

24 hours. The authors indicated that the ICC of 0.78 suggested that the measurements were sufficiently reliable.

McDonnell et al. (1987) examined the reliability of a fatigue test of the quadriceps muscle in nondisabled individuals using electrically elicited isometric muscle contractions. The Cybex II isokinetic dynamometer was used to evaluate the decline in peak torque over 50 contractions during two separate test sessions separated by seven days. The ICC, Pearson product moment correlation, and t-test were used to examine the reliability of the measures. The means of contractions 21 to 25 and 46 to 50 for test 1 and test 2 generated correlations of 0.82 and 0.92 respectively. The ICC values for the first and second set of contractions were 0.83 and 0.82, indicating acceptable reliability. The t-tests indicated that there was no significant difference when comparing test-retest percentages of torque decline.

Of the studies which involved spinal cord injured subjects, only three studies made reference to the reliability of the FES induced force measurements, however, no statistical analyses were reported. Stein et al. (1992) used a strain gauge in a specially designed apparatus to measure FES induced dorsiflexion of the ankle. The values were reported to be reproducible based on the consistent day to day fitting of the moulded piece of the measuring device. Bremner et al. (1992) measured quadriceps strength using a strain gauge cantilever beam and reported a repeatability of

plus or minus two Newton meters as determined by the mean difference in torque following consecutive strength measures for all subjects.

Duvoisin et al. (1986) described a laboratory designed system for quantification of muscle force produced during FES. Four muscle groups of the lower extremity were examined. The time frame of the testing and the subjects who participated in the study were not described. It was stated that the technique used offered accurate quantification of the muscle forces although no raw data or statistical analysis were included.

Of the studies reporting the use of the Cybex dynamometer to evaluate isokinetic FES induced contractions in paraplegics, no mention of reliability was given. Hjeltes and Lannem (1990) referred to an earlier study using the Cybex to evaluate torque and EMG responses during knee flexion and extension in nine able-bodied men (Hjeltnes & Pedersen,1983). Although the reliability for the able-bodied individuals was reported to be good, it cannot be assumed that the same reliability would be evident in the SCI population. Neither Edwards and Marsolais (1987) or Marsolais and Kobetic (1987) reported any statistical reliability coefficients nor did they make reference to any previously documented reliability studies.

The reliability of the measurement of FES induced muscle contractions in SCI could be affected by potential

sources of variability. Of particular concern were the potential effects of spasticity, medications and muscle temperature.

Rosenflack and Andreassen (1980) found that during voluntary submaximal isometric contractions of the tibialis anterior muscle, subjects with spasticity demonstrated fluctuations in torque measurements that were larger and slower than in normal subjects. Also, maximal torque in the patients with spasticity was 40% or less than that of normal subjects. Knutsson and Martensson (1980), evaluated isokinetic knee extension and flexion in subjects with spastic paresis. Involuntary co-activation of antagonistic muscles as measured by EMG recordings occurred frequently in the subjects with spasticity and were more pronounced with increased angular velocity. This co-activation resulted in decreased ability to produce torque and in some cases, inability to perform the movement.

Increased muscle tone and spasms can interfere with the use of FES (Cybulski et al.,1984). It is often noted that in studies involving FES with SCI individuals, the selection criteria stipulate a specific level of spasticity. Usually the level of spasticity allowable is described as low or minimal to moderate (Bremner et al.,1992; Ragnarsson,1988; Ragnarsson et al.,1988).

Medications that are related to musculoskeletal function, particularly antispasticity medications, have been

investigated in regard to their effect on strength. Smith et al.(1992), found that there was no significant difference in maximum isokinetic torque production for measurements taken. The multiple sclerosis patients were tested both before and after Baclofen treatment to allow the assessment of the effect of Baclofen on muscle strength. Patients with cerebrovascular accidents (CVA), were used in a study by Katrak et al.(1992) to determine the effect of Dantrium on muscle strength. It was found that the Dantrium did not significantly reduce the isokinetic maximal torque achieved in the paretic limb.

Rodgers et al.(1991) evaluated the musculoskeletal responses of complete and incomplete SCI individuals to an FES exercise programme. The medication schedules of the subjects were not altered however, 7 of the twelve subjects took antispasticity medications. Although the average change in strength for the group taking medication was higher, it was not statistically significant.

Environmental conditions can result in variation of the temperature of limb muscles by as much as 10^0 celsius (Holewijn & Heus,1992). Evidence has been shown that changing temperature of the extremities affected both the mechanical and metabolic properties of the muscles (Bigland-Ritchie et al.,1992; Edwards et al.,1972). The effect of muscle temperature on static and dynamic muscle strength has also been studied. Bergh and Ekblom (1979) evaluated maximal

strength of the knee extensors at varying intramuscular temperatures. It was found that peak torque declined as muscle temperature decreased and that the effect of temperature was greater for isokinetic measurements. Skin temperature and isometric grip strength were measured in a study evaluating the effects of temperature on muscle function (Holewijn & Heus,1992). The results indicated that cooling significantly reduced the average maximal force production as well as resulting in a slower build up of force.

E. SUMMARY

FES as used in disabled and nondisabled populations is complex and involves consideration of muscle physiology as well as stimulation parameters. It has been established that FES induced exercise can improve torque production in paralysed muscles of individuals with spinal cord injuries. There have been a variety of methods used to describe strength gains, most involving tests that were not specific to the exercises performed. Most of the studies did not report the reliability of the assessment tools utilized and many of the tools were specific to the individual research laboratories.

III. METHOD

A. SUBJECTS

The non-random convenience sample included 15 complete paraplegics and quadriplegics (see sample size calculation in Appendix E) with upper motor neuron lesions. The upper limit of spinal cord injury for participation in FES programs is currently defined at C4/C5 to ensure adequate ventilatory drive. The lower level of neurological injury is defined at T11/T12 such that the peripheral motor neurons below the level of injury remain functional (Phillips,1991).

Potential subjects were recruited by the investigator. Most of the research done using electrical stimulation involved small numbers of carefully selected individuals with spinal cord injury (Yarkony et al.,1992). This selection process was due to the fact that only a small percentage of the total population of spinal cord injured were potential users of FES and thus it was impossible to use random sample selection. Potential subjects were contacted by telephone and the purpose and the procedures of the study were explained. All subjects who agreed to participate were required to sign a consent form (Appendix C) prior to participation.

The subjects were accessed through the spinal cord injury program at the Glenrose Rehabilitation Hospital and

community organizations such as the Rick Hansen Centre and the Canadian Paraplegic Association. No attempt was made to control for subjects who were trained or untrained in terms of FES exercise. The subjects had to meet the following inclusion criteria:

1) be of good general health and have no current infections which required medical treatment
2) have a complete upper motor neuron lesion between C4/C5 and T11/T12 as determined by clinical classification
3) less than 10 years post injury. If it was less than 6 months from the date of onset, the subject must have been deemed medically stable by a physician
4) demonstrated an electrically excitable quadriceps muscle
5) spasticity level less than or equal to grade 2 as measured on the Ashworth scale (Appendix F). Muscle spasms should have been infrequent or controlled by medication (Phillips,1991)
6) absence of recent or current lower extremity fractures and a level of mild or moderate osteoporosis as evaluated on radiological examination (Ragnarsson et al.,1988; Phillips,1991; Arnold et al.,1992)

7) no recent or current pressure sores (Bremner et al.,1992; Phillips,1991)

8) no previous adverse reactions to FES

9) no signs or symptoms of autonomic dysreflexia during FES. If an autonomic dysreflexic reaction occurred during the study,it resulted in withdrawal of the subject from the study

B. PRE-TEST EVALUATION

When initially contacted, the potential subjects were asked questions (Appendix B) regarding their health, spasticity level, skin integrity and other information relating to the selection criteria, as a screening method. If the subject fit the criteria, he or she was asked to have an X-Ray taken of the right lower extremity at the Glenrose Rehabilitation Hospital. The cost of the X-Ray and other materials were covered by a research grant from the Glenrose Rehabilitation Hospital. If the X-Ray examination showed no evidence of fracture or a severe level of osteoporosis, the subject was asked to come for a pre-test assessment with the investigator. The subjects were asked to arrive for testing with an empty bladder to minimize effects of spasticity due to bladder fullness (Bromley,1976). At the pre-test assessment, spasticity was tested (Appendix F) while the subjects were in the seated position and then recorded (Appendix B). If within an acceptable level as outlined in

the inclusion criteria, they were then tested for an excitable quadriceps response to FES while sitting in the wheelchair. Blood pressure was monitored automatically to determine if there was an autonomic dysreflexic response. Providing there was no dysreflexic response, testing commenced in the same session. As most subjects followed a specific schedule for medication intake, they were asked to ensure that this schedule was consistant for both days of testing.

C. TORQUE MEASUREMENT

The subjects FES induced knee extension strength was evaluated using the KinCom isokinetic dynamometer (Chattecx Corp.) which was capable of measuring torque during concentric and eccentric contractions. The device used was able to measure strength isometrically (0^0/sec), isotonically, and isokinetically (velocities up to 210^0/sec). Velocities between 30^0/sec and 180^0/sec have been used for reliability studies of isokinetic measurements on the KinCom (Harding et al.,1988; Tredinnick & Duncan,1988; Tripp & Harris,1991; Durand et al.,1991). For this study, two test speeds were chosen, 30^0/sec and 90^0/sec, in order to avoid possible spastic reactions that might occur with higher velocities. Mizrahi and Angel (1980) evaluated the impairment of voluntary movement as a result of spasticity and found that with movement at higher velocities

antagonistic restraint could be strong enough to arrest movement. Angular velocities of 30^0 and 90^0/second had been utilized in a study involving SCI subjects (Hjeltnes & Lannem,1990), although rationale for selection of these speeds was not stated. Edwards and Marsolais (1987) used an angular velocity of 60^0/sec in the evaluation of three paraplegics. It was found that faster speeds caused the leg to hyperextend and slower speeds were less specific to the velocity of walking. Even though the test speed might be more specific to the velocity seen during walking, the test position was not. It was felt that an angular velocity of 120^0/sec was too fast and could result in the difficulties already mentioned. The two chosen angular velocities were slower speeds and yet not too similar.

Farrell and Richards (1986) have reported that the KinCom device operating systems, lever arm position, velocity and force measurement were both valid and reliable. The reliability of the KinCom for isokinetic measurements of knee extension in able-bodied males (Tredinnick & Duncan,1988) and females (Hanten & Ramberg,1988) has been reported as good, ($r= 0.75 - 0.97$) except for eccentric torque measurements at 60^0/second ($r= 0.47$).

The subjects were seated on the KinCom chair with the hip joint flexed to approximately 90 degrees and the back supported. Velcro straps were used for stabilization of the trunk, pelvis and thigh of the test leg. The upper

extremities remained at rest in the subject's lap. The centre of rotation of the dynamometer lever arm was aligned with the lateral epicondyle of the right femur and the lever arm length was adjusted so that the distal end of the resistance pad rested approximately 2 cm above the medial malleolus. The center of rotation was adjusted to decrease the slippage between the leg and the pad during movement. The length of the lever arm was recorded and remained consistent for each individual for each test session. Gravity compensation was used for all tests.

D. MUSCLE STIMULATION

The electrical stimulation was delivered using the Quadstim (Biomech Designs Inc.) four channel neuromuscular stimulator with adjustable parameters. The frequency, pulse width and current at each of the setting increments was examined prior to each test session using a digital storage oscilloscope (Philips, PM3375). The stimulation parameters chosen, based on the literature (Appendix G) included: frequency of 30 Hz, pulse width of 300 microseconds using a monophasic constant current. Although Susak et al. (1986) determined that the time to maximal fatigue in five paraplegic subjects was longest when using a frequency of 20 Hz, the frequency of 30 Hz was chosen in order to produce a contraction that would be closer to maximum (Benton et al.,1981; Hainaut & Duchateau,1992). The intensity of

stimulation required to produce a maximal contraction was determined using an incremental test. A set of concentric contractions were measured with each successive contraction at a higher output setting on the stimulator. The results of the set of contractions was viewed to determine at which setting maximal muscle contraction occurred. The setting for the submaximal contraction was the level at which the current output of the stimulator was 20% below that which generated the maximal contraction. There was a two minute rest after the incremental test prior to any other testing. Although in most reliability studies maximal contractions are examined, it was also of benefit to establish reliability for FES induced submaximal contractions as they have been used in studies of motor unit recruitment characteristics (Knaflitz et al.,1990; Levy et al.,1990).

Self adhesive surface electrodes were used to eliminate potential movement during contractions. One set of electrodes were used for each subject to ensure consistency of conduction of the stimulation current. The two electrodes were approximately 4cm x 9cm for quadriceps muscle stimulation. McNeal and Baker (1988) found that the forces produced by the quadriceps muscle were not significantly affected by electrode size.

Before each session, the skin temperature at the site of electrode placement was measured using the YSI scanning thermometer (Yellow Springs Instrument Co., Ohio, model

47TD) as an estimate of muscle temperature. Changes in muscle temperature have been shown to result in alterations of torque production (Holewijn & Heus,1992; Bergh & Ekblom,1979). Also, the hamstrings and quadriceps muscles were passively stretched while the subject was in the seated position to reduce the effect of spasticity during testing (Bromley,1976). The stretch was applied while the subject was seated as this was the position for testing.

The skin was prepared by shaving excess hair from the site of electrode placement and wiping the skin with alcohol swabs. The electrodes were placed using a longitudinal orientation (Brooks et al.,1990). The proximal electrode was placed 5 cm from the anterior superior iliac spine near the femoral nerve (as measured in sitting) and the distal electrode was placed 5 cm from the superior border of the patella near the motor point of the vastus lateralis. This placement was chosen based on a study by McNeal and Baker (1988) as the placement described was in the two regions of excitability found for the quadriceps muscles. The distal region of the quadriceps was found to have a much broader region of excitability and this finding was supported by the research of Ferguson et al. (1989). It was determined that there was no significant difference in torque production with vastus medialis, vastus lateralis and rectus femoris motor point placement. Markings were placed on the leg around the perimeter of the electrode to ensure consistency

of electrode placement.

E. INTRA-SESSION

Each subject performed five FES induced maximal concentric knee extensions at the first test speed. Test speed order was determined randomly for each subject. Each contraction was separated by a 10 second pause. In the literature, the rest periods between contractions varied from five to 30 seconds. It is generally accepted that an on:off ratio of 1:3 (seconds) is appropriate (Benton et al.,1981). Cox et al. (1986) found that the least decrement of torque production during a 10 second contraction at a frequency of 50 Hz was evident with a 50 second rest interval. Thus, the on:off ratio would be 1:5 (seconds). In this study, the stimulation was not on for more than two seconds due to the angular velocity of testing, therefore, a pause of 10 seconds established an on:off ratio of 1:5.

After maximal concentric knee extension was tested at the first test speed, there was a two minute rest prior to testing the submaximal contraction at the first test speed. There was a five minute rest prior to testing maximal and submaximal contractions at the second test speed. Pournezam et al. (1988) demonstrated that after continuous stimulation of the quadriceps in SCI individuals, the force produced dropped to 50% of its initial value after 63 seconds. After a five minute rest period, the rectus femoris had recovered

85% of its initial knee moment. After 30 minutes recovery was up to 95 percent. During this study, the total time of stimulation, which was intermittent, did not exceed 20 seconds so a five minute rest was considered adequate.

In order to determine intra-session reliability, the subjects were tested for both maximal and submaximal concentric knee extension at both speeds after a 45 minute rest period which was adequate for muscle recovery (Pournezam et al.,1988). The order of testing remained the same as for the first session. Between the first and second sessions, the electrodes were not removed but, the subject did transfer off of the KinCom chair. This was done to avoid excessive pressure on the buttocks of the subjects, as the surface of the KinCom chair was quite hard.

F. INTER-SESSION

To determine inter-session reliability, the subjects were tested at both angular velocities 4-7 days later. As there was no literature to substantiate the selection of this time frame, it was based on clinical observations that this time frame was short enough so that changes due to progression of muscle atrophy would have no effect. The subjects were tested at both speeds,in the same order as for the first session, and performed both maximal and submaximal concentric contractions as described in the procedure for the first session. Results from this session were compared

to the results of the first session so that consistency was maintained by comparing the first tests done on each test day.

G. DATA ANALYSIS

Peak torque values from the best three of the five test repetitions of maximal and submaximal contractions at each test speed were averaged and used for data analysis. It was necessary to be selective in choosing the test repetitions to analyze as some contractions were obscured due to spasticity and there was an obvious delay in the initiation of the FES in a few. Descriptive statistics, means and standard deviations, were used to describe the peak torque values and the subject demographics. Intraclass correlation coefficients (ICC - type 1,1; Shrout & Fleiss,1979) were used to examine intra-session and inter-session reliability of the average torque measurements for each type of contraction. Statistical significance of the ICC was evaluated by the calculation of the 95% confidence limits for each correlation coefficient (Stratford,1989). The ICC was used along with a z-test of significance to determine any difference in the reliability for the two selected velocities. An F-test was used to evaluate differences between the skin temperature measures taken prior to each test session. An alpha level of $p < 0.05$ was used. The ICC was the most appropriate statistic as it assessed the degree

of agreement between repeated measures and took into account systematic error. The standard error of measurement (SEM) was also calculated. The SEM provides a number that represents the variance of a single score when a measurement is done more than once (Rothstein,1985). Therefore, the clinician has a more precise index to interpret if the change in the variable of interest is due to true change or error. For the SEM to be considered clinically acceptable, it must be interpreted with consideration of the scores for the variable of interest.

TABLE 3.1

Data analysis (ICC and SEM) for intra and inter-session

TOC	VEL	INTRA- SESSION		INTER- SESSION	
		ICC	SEM (Nm)	ICC	SEM (Nm)
	30^0/sec				
MAX	90^0/sec				
	30^0/sec				
SUB	90^0/sec				

Intra-session session 1,test 1 to session 1,test 2 (same day)
Inter-session session 1,test 1 to session 2,test 1 (4-7 days later)

ABBREVIATIONS USED IN TABLE: TOC- Type of Contraction; VEL- Velocity; MAX- maximal; SUB- submaximal; ICC- Intraclass Correlation Coefficient; SEM- Standard Error of Measurement; sec- second

IV. RESULTS

A. DESCRIPTION OF SUBJECTS

The fifteen subjects who participated in the study ranged in age from 18 - 42 years (mean age: 27.2). There were 14 males and one female tested. All subjects were motor and sensory complete spinal cord injured individuals with a level of injury ranging from C6 - T10. The level of spasticity as measured on the Ashworth Scale was less than or equal to grade 2 in all cases. Six of the subjects had been or were involved in an FES training program and nine subjects had never used FES before. Complete descriptive data for the 15 subjects is presented in TABLE 4.1. The subjects who participated in this study were very similar in characteristics to those currently described in the literature (Appendix H).

B. INTRA-SESSION AND INTER-SESSION RELIABILITY

The average of the three best peak torque measurements for each contraction type at each velocity was used in the calculations of the intraclass correlation coefficients (ICC). The raw data for all the subjects is presented in Appendix I. The ICC calculated for the intra-session reliability ranged from 0.89 to 0.98 and the inter-session reliability ranged from 0.94 to 0.97. The results indicate

very good reliability of the repeated measures. The reliability coefficients for each contraction type at each velocity are presented in TABLE 4.2. The statistical significance of the reliability coefficients was determined by the calculation of the 95% confidence limits (TABLE 4.3).

The standard error of measure (SEM) ranged from 2.8 Nm to 5.4 Nm which indicates that for a given torque measurement, the true score will be encompassed within a range of the measured value plus or minus the SEM. Table 4.4 indicates the means, standard deviations, minimal and maximal values for each test session. The standard deviation was quite large in all cases and this was likely due to the variance of scores among the subjects.

C. DIFFERENCE BETWEEN CORRELATION COEFFICIENTS

A Z-test of difference between the correlation coefficients was calculated (Appendix J) to determine if there was a significant difference between the reliability coefficients for contraction type and velocity. A Z-test was also calculated to determine if there was a significant difference between the intra-session and inter-session reliability coefficients. In all cases, maximal contraction was tested first. Random assignment of velocity resulted in 5 subjects being tested at 30^0/second and ten subjects being tested at 90^0/second. The calculated values are presented in TABLES 4.5 and 4.6. As all values did not exceed plus or

minus 1.96, it was determined that there was no significant difference in the reliability of measurements based on contraction type, velocity or session.

D. SURFACE TEMPERATURE MEASURES

Temperature measures were taken prior to each test session in order to evaluate potential effect of skin temperature on the reliability of the measurements. According to the results of the F-Test presented in TABLE 4.7, there was no significant difference between the temperature for each session.

TABLE 4.1

Descriptive Data of the 15 FES Subjects

N	SEX	AGE(yrs)	LEVEL	YR/INJ	SPAS	FES/T
1	M	19	T9	0.08	2	no
2	M	28	C7	10.0	1	no
3	M	21	T5	2.5	2	yes
4	M	42	C7	3.5	2	yes
5	M	27	T10	8.0	2	no
6	M	30	C7	3.5	2	yes
7	M	38	C7	0.6	1	no
8	M	33	C7	0.16	1	no
9	M	28	C6	0.33	2	no
10	M	22	C6	5.5	2	no
11	M	18	T6	0.33	2	yes
12	M	26	C8	8.0	2	yes
13	F	18	C7	2.5	1	no
14	M	26	T4	10.0	1	yes
15	M	32	C7	0.25	1	no

ABBREVIATIONS USED IN TABLE: N - subjects, YRS/INJ - years since onset of injury, SPAS - Ashworth scale spasticity scores (Appendix F), FES/T - FES trained.

TABLE 4.2

Intraclass Correlation Coefficients for Intra-session and Inter-session Measurements

TOC	VEL	INTRA- SESSION		INTER- SESSION	
		ICC	SEM (Nm)	ICC	SEM (Nm)
	30^0/sec	0.98	3.7	0.95	5.4
MAX	90^0/sec	0.96	3.8	0.94	4.7
	30^0/sec	0.97	2.9	0.97	3.1
SUB	90^0/sec	0.89	3.9	0.94	2.8

ABBREVIATIONS USED IN TABLE: TOC- Type of Contraction; VEL- Velocity; MAX- maximal; SUB- submaximal; ICC- Intraclass correlation; SEM- standard error of measurement; Nm- Newton meters; sec- second

TABLE 4.3

95% Confidence Limits for the Intraclass Correlation Coefficients

CONTRACTION	VELOCITY	INTRA-SESSION	INTER-SESSION
		95% CL	95% CL
	30^0/sec	0.94 - 0.99	0.87 - 0.98
MAXIMAL	90^0/sec	0.88 - 0.98	0.82 - 0.98
	30^0/sec	0.92 - 0.99	0.90 - 0.99
SUBMAXIMAL	90^0/sec	0.72 - 0.96	0.85 - 0.98

ABBREVIATIONS USED IN TABLE: CL- Confidence Limit; sec- second

TABLE 4.4

Descriptive Analysis for Test Scores

TOC	VEL	SESSION	MEAN	SD	MIN	MAX
MAXIMAL	30^0/sec	1	35.6	25.4	6.0	100.0
		2	33.4	26.7	5.0	103.6
		3	36.6	24.7	5.7	88.7
	90^0/sec	1	28.3	19.1	5.0	77.3
		2	25.3	17.8	3.7	69.0
		3	27.5	17.7	2.7	62.7
SUB	30^0/sec	1	21.3	17.2	3.0	57.7
		2	18.7	16.5	2.3	55.7
		3	20.7	15.6	3.0	51.0
	90^0/sec	1	17.4	12.6	2.7	46.7
		2	14.3	11.2	2.6	36.3
		3	16.6	11.0	2.7	35.0

ABBREVIATIONS USED IN TABLE: TOC- Type of Contraction; VEL- Velocity; SD- standard deviation; MIN- minimum score; MAX- maximum score; SUB- submaximal; sec- second

TABLE 4.5

Results of the Z-tests for the Analysis of Difference Between Correlation Coefficients for Contraction Type and Angular Velocity

ICC COMPARISON	RESULT
MAX 30 : SUB 30	-0.179
MAX 90 : SUB 90	0.643
MAX 30 : SUB 90	0.302
SUB 30 : SUB 90	1.125

ABBREVIATIONS USED IN TABLE: ICC- Intraclass Correlation Coefficient; MAX- maximal contraction; SUB- submaximal contraction; 30- 30^0/second; 90- 90^0/second

TABLE 4.6

Results of Z-tests for the Analysis of Difference Between Correlation Coefficients for Intra-session and Inter-session Measurements

	MAXIMAL	SUBMAXIMAL
30^0/second	1.233	0
90^0/second	0.659	-0.836

TABLE 4.7

Summary of F-Test for Skin Temperature Measurements

	MEAN SQUARES	F RATIO	PROBABILITY
BETWEEN	6.0222	3.04	0.06
WITHIN	1.9778		

V. DISCUSSION

A. INTRA/ INTER-SESSION RELIABILITY

All fifteen subjects were able to generate measurable maximal and submaximal FES induced contractions using the outlined protocol. There were no complications in terms of autonomic dysreflexia, skin abrasions or fractures incurred at any time of testing.

The results of this study indicate that the protocol used to assess FES induced knee extension was reliable as determined by the ICC values which ranged from 0.89 - 0.98. Statistical significance is evident by the ranges for the 95% confidence limits. There was no statistically significant difference between reliability coefficients which would indicate that a specific contraction type or velocity was more reliable.

Similar results for FES induced isometric knee extension have been reported (McDonnell et al.,1987; Binder-Macleod & Barker,1991; Binder-Macleod & McDermand,1992). These studies involved able-bodied subjects and tested isometric contractions making comparisons with the present study difficult. It is important that reliability be established for each movement and each velocity for various patient populations. Only then can one know if the measurements give clinically meaningful data.

The test protocol was found to be reliable for both test velocities. It is evident from the raw data (Appendix H) that knee extension torque at the faster speed was less than that produced at the slower speed. Physiologically, there are fewer links formed between the actin and the myosin and the bridges that do form detach more quickly. Thus, when the muscle is required to shorten more rapidly against a constant load, there is less tension produced (Gowitzke & Milner,1981). The lower torque values at higher speeds could be related to fibre type atrophy. Thorstenssson et al. (1976) compared dynamic strength of the quadriceps of 25 healthy male subjects. He demonstrated a correlation between the ability to produce high force at high angular velocities and type II muscle fibres. These findings were based on the explanation that dark staining fibres (fast twitch), have higher myosin ATPase activity which is inversely related to muscle contraction time. In lesions involving the upper motor neurons, as is the case with SCI, there is often noted to be type I and II muscle fibre atrophy when compared to normals (Martin et al.,1992). The SCI subjects had a higher percentage of type II fibres (dark staining) as compared to normals who had a higher percentage of type I fibres (light staining). The myofibillar ATPase activity of the SCI subjects was markedly decreased. The results indicate that fibre type classification may be a reflection of the staining characteristics and not

necessarily representative of the contractile properties. No conclusion can be drawn regarding fibre type atrophy in this study as muscle biopses were not performed.

Bohannon (1987) demonstrated that the mean isokinetic knee extension torque decreased with increasing speed on both the paretic and non paretic side of 27 hemiparetic patients. Griffen et al. (1986) studied patients with varying neuromuscular disorders and also noticed decreased torque output at faster angular velocities. Although the muscle contractions tested in this study involved electrical stimulation, it would still be expected that a similar force-velocity relationship would be present.

Reliability was also high for both types of contractions tested, maximal and submaximal. In most reliability studies involving normals, maximal voluntary contractions are tested as it would be too difficult for a subject to consistantly produce a force that was a certain percentage of maximum. An FES induced contraction can produce submaximal force as the current output of the stimulator can be held constant. It may be important to be able to test FES induced submaximal contractions in SCI, particularly because of the potential safety concerns in regard to bone fracture. Maximal testing may not be required if it is discovered that the subject can produce the torque required for a specific function at a submaximal level. There may also be implications in regard to determining the

optimal levels for FES training.

B. POTENTIAL SOURCES OF VARIABILITY

It was taken into consideration that there could be an effect on the reliability of the measurement due to spasticity, medications or change in temperature at the skin surface overlying the quadriceps muscle.

In regard to spasticity, Knutsson and Martensson (1980) showed that in patients with spastic hemiparesis or paraparesis, there was reduced torque production particularly at higher speeds due to antagonistic restraint. Also, some subjects were unable to produce measurable torque at higher speeds due to spasticity. Reliability was not specifically examined as this was not the purpose of the study. However, it is stated that each movement was tested repeatedly until 2 - 3 consecutive trials gave similar recordings. Tripp and Harris (1991) examined reliability for isokinetic knee extension in patients with spastic hemiparesis. Although reliability was indicated to be good, (ICC: 0.91-0.97) the level of spasticity was low. Only four of the 20 subjects had a spasticity level of grade 3; the remainder had a grade 2 or less. The spasticity of the subjects in this study was measured and was required to be low (less than or equal to grade 2) for inclusion into the study. The results of this study indicate that patients with a low level of spasticity could produce a measurable torque

at speeds of 30^0 and 90^0/second. Given these results, it can be concluded that patients with a low level of spasticity could produce reliable results when tested isokinetically. One cannot draw conclusions regarding reliability of measurement with patients who have greater levels of spasticity.

This study did not attempt to control for the type of medication that the subjects were taking. It was asked of the subjects that timing and dosage of the medications remain consistant during their involvement in the study. A list of medications taken by the subjects was recorded in the event that a pattern emerged for the subjects on similar medications. Previous studies involving neurological patients have shown little effect of medication on torque production, specifically medications used to control spasticity. Katrak et al. (1992) studied the effects of dantrium on patients with cerebral vascular accidents while Smith et al. (1992) studied the use of baclofen with multiple sclerosis patients. In both studies, the medications had no effect on maximal isokinetic torque production.

Both intramuscular and surface temperature have been used to evaluate the effects of muscle temperature on static and dynamic strength. Studies have shown that reduced muscle temperature results in a decline of the torque production (Holewijn & Heus,1992; Bergh & Ekblom,1979). In the present

study, it was shown that the surface temperature, measured prior to each session, was not statistically different between test sessions. It appears that the reliability of the test protocol was not adversely affected by the skin surface temperature. No conclusions can be made regarding the effects on the reliability of the measurements had there been significant difference in skin surface temperature.

No attempt was made to control for current or previous training with FES. Both trained and untrained individuals were included in the study. It was apparent from this study that the protocol outlined was reliable for complete SCI individuals regardless of experience with FES training. The raw data (Appendix H) indicated that trained individuals produced higher torque values than most of the untrained individuals. These results are consistant with those of Rabischong and Ohanna (1992) who demonstrated that there was a significant higher quadriceps torque output for subjects who have undergone FES training. Average peak torque values ranged from approximately 30 Nm to 100 Nm. It was also evident that there was a large standard deviation for all measurements which could be explained by the fact that by using FES trained and untrained individuals, there was a greater variability amoung the peak torque measurements. These values were similar to those reported by Hjeltnes and Lannem (1990) who also measured SCI subjects isokinetically at 30^0 and 90^0/second (refer to Appendix H for the torque

submaximal contraction could be compromised by the accuracy of the intensity scale on the Quadstim. The interval scale of the stimulation intensity (ie. 0 - 10) is somewhat subjective because it is a sliding apparatus and therefore continuous. It is dependent on the examiner to place the sliding knob in exactly the same spot for each test as was done in this study. In addition, the current output at each level of the scale was determined on the oscilloscope prior to the testing of each subject. The output levels were found to remain consistent throughout the duration of the study.

C. STANDARD ERROR OF MEASUREMENT

It is not sufficient to accept the statistical significance of a measurement based on the reliability coefficient alone. It is important to view the outcome in terms of standard error of measurement (SEM). The SEM calculated in this study ranged from 2.8 to 3.9 Nm for the submaximal contractions and 3.7 to 5.4 Nm for the maximal contractions, indicating the amount of possible error that could occur in either direction. The mean values of the outcome measures must be considered when determining if the SEM is clinically acceptable. Compared to the mean torque values in the range of 25 to 35 Nm for maximal contractions and 15 to 21 Nm for submaximal contractions, the reported values for the SEM appear to be within an allowable range. The SEM provides the clinician with a valuable reference for

values for the SEM appear to be within an allowable range. The SEM provides the clinician with a valuable reference for determining true change when evaluating patient progress. This study would indicate the measurement protocol has both statistical and clinical significance.

D. CLINICAL RECOMMENDATIONS

Based on the findings of this study, following the protocol as outlined for use with the KinCom isokinetic dynamometer, reliable results can be obtained. Reliability will be evident for measurements taken on the same day and within one week. Particular attention should be paid to the parameters set on the stimulator which were described in the methods. Results may not be as reliable for different parameters. Maximal and submaximal contractions of isokinetic concentric knee extension are reliable when measured at two angular velocities. Further study is required to determine if the protocol used in this study is reliable for other angular velocities which may be considered clinically important.

Reliability was only tested for concentric contractions as it was felt that it was important to test a muscle in a similar manner to which it would be used functionally. From the results of this study, conclusions cannot be made regarding the reliability of other contraction types such as isometric or eccentric.

Useful clinical information regarding torque production in paralysed muscle can be obtained when using the methods as described and providing that the patients are similar in characteristics to those that participated in this study. Such measurements could be used to characterize the neuromuscular capabilities of the SCI patients evaluated and could also serve as reference data to evaluate effects of training programmes.

VI. SUMMARY AND CONCLUSIONS

A. SUMMARY

The objectives of this study were to determine the intra-session and inter-session reliability of a protocol using the KinCom to measure the FES induced knee extension in spinal cord injured individuals. Fifteen subjects (14 male ,1 female), aged 18 to 42, all with complete spinal cord injuries between the levels of C6 and T10 made up the study population. Pre-test evaluation, including radiological examination were used to determine the suitability of the subjects prior to testing.

Reliability was determined for maximal and submaximal contractions at two angular velocities (30^0 and 90^0/second) for measurements taken on the same day and measurements taken within one week. A pulse frequency of 30 Hz and pulse duration of 300 microseconds was used for all subjects. Each subject performed four sets of five contractions to include all combinations of contraction type and angular velocity.

The peak torque of the best three contractions for each set was used in the statistical analysis. Reliability was determined using intraclass correlations (ICC). A Z-test of significance was used to determine any significant difference between the correlation coefficients and the standard error of measurement was also calculated.

B. CONCLUSIONS

Based on the study conducted and described above, the following conclusions were made:

1. Using the methods described, the KinCom can reliably measure FES induced maximal and submaximal knee extension in individuals with complete SCI.
2. Reliability for measurements taken at angular velocities of 30^0 and 90^0/second was acceptable at 0.89 to 0.98.
3. No significant difference of reliability coefficients was found between the different contraction types and angular velocities or between intra-session and inter-session measurements. Therefore, no one contraction type, angular velocity or session were found to produce more reliable results.
4. The standard error of measurement was low as compared to the mean scores, providing clinicians with important information regarding the interpretation of results with respect to true changes in measurement.
5. The test protocol is reliable for SCI individuals regardless of previous experience with FES and those who demonstrate a low level of spasticity.

On the basis of these conclusions, it can be stated that the protocol used in this study can reliably determine FES induced knee extension produced in the paralysed muscle of SCI individuals.

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APPENDIX A

KINCOM SYSTEM CALIBRATION CHECK

KIN-COM® System Calibration Check

CAUTION: This procedure should not be done by clinical personnel unless directed by Chattecx service to do so. If the adjustments listed below can not be obtained, a complete calibration must be performed. All user potentiometers are located on the top the computer mounted on the rear of the KIN-COM® and identified by a decal located just above the computer.

Touchscreen Calibration Procedure

If the unit is equipped with Touchscreen, the following procedure calibrates the monitor.

A. Press the alternate, control, and delete key on the keyboard simultaneously to reboot system. Allow computer to respond before proceeding to the next step.

B. Follow instructions on screen and press where indicated.

C. Press the OTHER key on the screen.

D. Press the SETUP key on the screen.

E. Type T on the keyboard and press return.

F. Follow instructions called out on the screen.

G. To return to the main menu, type in M on the keyboard and press return.

1. **Power up the unit**. The Main Menu will appear, use the (ESC) key to bring up the Utility Menu. From the Utility Menu, type the word **TEST** and read the message that appears on the screen. In response to the mesage, MAKE SURE THE ACTUATOR ARM AND EMERGENCY STOP HUB ARE REMOVED FROM THE ACTUATOR SPLINE, then type the word **YES**. The KIN-COM® Test Program Main Menu will be displayed on the screen.

To reach the KIN-COM® Test Program Main Menu on a unit that is equipped with Touchscreen follow these instructions:

A. Reboot the system by pressing the alternate, control, and delete key on the keyboard simultaneously. Allow the computer to respond before proceeding.

B. Press where indicated on screen.

C. Press OTHER on the screen.

D. Type in the word TEST at the keyboard. NOTE: These letters will not appear on the screen. Press the Return key. Read the message that appears on the screen. Before responding to the message, MAKE SURE THE ACTUATOR ARM AND THE MECHANICAL SAFETY HUB ARE REMOVED FROM THE ACTUATOR SPLINE. then type the word YES. The KIN-COM® Test Program Main Menu will be displayed on the screen.

2. **Preliminary Speed /Force Zero**

A. Select "Test the KIN-COM® System screen by typing (T).

B. Insure that the indicated Vel: (velocity indication located in the upper right hand corner of the screen) reads 0 ± 1. If incorrect, adjust User potentiometer R5 (Speed Zero) for a correct indication. Assure this signal is steady and not fluctuating. Fluctuations in the signal may indicate problems existing in either the grounding of the machine or the control circuitry.

C. Install the Actuator Arm onthe Actuator Spline.

D. Install the Load Cell Assembly on the Actuator Arm and position the arm to a true Vertical (arm pointing up) position.

E. INSURING NO FORCE IS BEING APPLIED TO THE LOAD CELL. Observe that the Force: (the force reading is located in the same area as the velocity reading in 2.B) indication is less than 10 Newtons. If incorrect, adjust R3 (Force Zero) potentiometer for a displayed force value of 0 Newtons.

F. Type (Q) to return to the KIN-COM® Test Program Main Menu.

3. **Servo Gain and Balance Adjustment**

CAUTION: THIS PROCEDURE WILL UTILIZE HIGH SPEED SHAFT ROTATION. INSURE THE ACTUATOR ARM /LOAD CELL ASSEMBLY AND THE EMERGENCY STOP HUB ARE REMOVED FROM THE ACTUATOR SHAFT.

A. Select the Velocity Calibration Screen by typing (V).

B. Turn the MOTOR to ON by depressing the (ENTER) key. The Motor will start and the Motor Status will indicate ON.

C. Turn the Dump to ON by depressing the [ENTER] key. The Dump Valve will activate even though the Dump Status indicates OFF. The wrong Dump Status indicated at this time results from the removal of the Emergency Stop Hub. DISREGARD THE DUMP STATUS.

D. With the cursor under Speed press the [ENTER] key, type **140**, then press the [ENTER] key again. The actuator will start rotating.

E. For the following steps, utilize the degrees/sec. indication under VELOCITY 180 degrees. Ignore the numbers in the parentheses.

F. Observe the Angle indication. The display should indicate ± 140 degrees/sec. ± 2 degrees/sec. Adjust R1 (Servo Valve) and R2 (Servo Gain) potentiometers for a displayed Angle indication of ± 140 degrees/sec. You should be able to obtain equal + and - numbers by adjusting R1 (Servo Zero). By adjusting R2 (Servo Gain), both + and - numbers should move equally in the same direction. These two potentiometers interact with each other, so it will be necessary to adjust between the two until you obtain ± 140 degrees ± 1 degree/second.

G. Repeat steps 3.F. until no further improvements are necessary.

H. With the cursor under Speed, press the [ENTER] key, type **0**, and again press the [ENTER] key. The actuator should stop rotating and remain motionless. If motion is observed, either the Servo Balance/Gain adjustment must be repeated or a malfunction exists.

I. Install the Actuator Arm/Load Cell Assembly on one of the Actuator Spline shafts and the Mechanical Safety Stop Hub on the other Actuator Spline shaft.

J. The displayed Dump Status should change to ON, and the Red INSTALL STOP Status indicator on the ERGO Arm Tray should go out.

K. Return to the KIN-COM® Test Program Main Menu screen by typing [Q].

L. Type the [X] key to exit to the KIN-COM® Operating Program.

APPENDIX B

PRE-TEST QUESTIONNAIRE

Pre-test Questionnaire

Subject_____

Level of Injury_____

Years since onset_____

Present infections requiring medication? yes_____ no_____

Describe your level of spasticity:

none_____ mild_____ moderate_____ severe_____

Ashworth scale measurement (measured by investigator)

1____ 2____ 3____ 4____

Any recent or current skin problems? yes____ no____

If yes, describe_____

Any previous or recent leg fracture that you are aware of?

yes____ no____

Any previous FES training? yes____ no____ unsure____

Any previous bad reactions to FES? yes____ no____ unsure____

List the medications you are currently taking and the dosages:

APPENDIX C

CONSENT FORM TO PARTICIPATE

Consent Form to participate in the project entitled:

"Intra-session and intersession reliability of isokinetic FES induced knee extension in spinal cord injury"

Principle Investigators: Laura May BHSc.PT
David Magee Ph.D
Robert Burnham M.D.

The KinCom is a computerized device that measures muscle strength. The purpose of this study is to see how consistent the KinCom is at measuring strength produced by electrical stimulation when people with spinal cord injuries are tested at different times.

If you agree to participate, you will attend two test sessions within a one week period. Before the first test session you will have an X-Ray taken of your leg to make sure that you do not already have any broken bones. The first test session will take approximately two hours and the second test session, within one week, will take approximately one hour. Each test session involves electrical stimulation of the thigh muscle which is done using surface electrodes.

There are no direct benefits to you personally. However, your participation will give the researchers important information that can be used in other studies and in the treatment of spinal cord injuries. There are possible risks involved when using electrical stimulation on paralysed muscles. The risks are not likely but are potentially serious. Therefore, you will be closely supervised to ensure safety. The possible risks which could cause testing to be stopped include:

-symptoms of autonomic dysreflexia (headache, facial flushing, sweating or high blood pressure)
-breaking a bone during the electrical stimulation
-a skin reaction or burn from the electrodes

Participation in the study is completely voluntary and you may withdraw at any time without any effect on your present or future medical care. Results from this study will be shared with other health care professionals but your identity will remain strictly confidential. This confidentiality will be ensured by using numbers only to identify each subject. The principle investigator will be the only person with access to the names of the subjects. All information will be kept locked in the office of the principle investigator.

I understand that my signature means:

1) that I have read this form
2) that all terms have been explained to me
3) that I have had the opportunity to ask whatever questions I desire and they have been answered to my satisfaction
4) that I accept the outlined risks and voluntarily agree to participate knowing that I may withdraw at any time, without any effect on present or future treatment
5) I will receive a copy of the consent form

If I have any further questions about the study, I can contact Laura May at 492-5983 or 478-9152.

Study Participant_____

Witness_____

Principle Investigator_____

Date_____

APPENDIX D
DEFINITIONS AND SAFETY PROTOCOLS

Definitions and Safety Protocols

Autonomic Dysreflexia

a result of disruption of control of the autonomic nervous system in individuals with spinal cord injury above the level of T6

signs and symptoms - headache, facial flushing, sweating, systolic and or diastolic BP rise greater than 50% of resting value, bradycardia or tachycardia

action - assume sitting position, check for possible sources of noxious stimuli e.g. blocked catheter, tight clothing etc., monitor blood pressure (if possible); if symptoms persist for more than five minutes seek medical assistance

Fracture

a break in the bone as detected by an X-Ray

as a fracture may occur during FES, detection would be made by recognition of the symptoms of autonomic dysreflexia as these symptoms would be the result of the presence of a noxious stimuli

Burn

a redness of the skin under the area of the electrode, also may be accompanied by blisters

Safety Protocol for the above conditions:

as per GRH Policies and Procedures - No. 7.4 (see next page)

GLENROSE REHABILITATION HOSPITAL

HOSPITAL POLICY/PROCEDURE

ISSUED BY:	President	NO:	7.4
DISTRIBUTION:	Manual Holders	ISSUE DATE:	Feb. '79
SUBJECT:	MEDICAL EMERGENCIES	LAST REVIEW:	Jul. '90
		REVIEW RESP.:	V-P, Medical

I. BACKGROUND

The purpose of this Policy is to ensure that medical emergencies are acted upon in an effective manner.

II. POLICY

All staff should be aware of what to do when they are confronted with a medical emergency on Hospital premises. A medical emergency is defined as any life threatening situation or situation which requires immediate assistance and which may involve a patient, staff, or visitor.

III. PROCEDURE

Person Identifying the Emergency

1. Summons help and have someone dial the "MEDICAL EMERGENCY" number "111" stating "CODE I" and exact location.

2. Institutes help to the best of ability. Applies cardio-pulmonary resuscitation as required and able. Resuscitation will be continued or taken over by persons trained in C.P.R. as soon as available.

Switchboard Operator

1. Announces "CODE I" and location three times over emergency override paging system.

2. Notifies those on group pocket page, including stations 33, 41, 201; Administrative Officer; Security staff; and, selected in-house physicians. (Note: Security will notify Staff Health Nurse if incident involves a staff injury or emergency.)

3. Telephones Stations 33, 41, and 201.

4. Pages "CODE I IS NOW OVER" when authorized by Assistant Director of Nursing/Administrative Officer.

III. PROCEDURE

Nursing Response Team will arrive with emergency equipment and direct the emergency response. The first in-house physician to arrive will take charge (until or unless this is designated to another physician or ambulance personnel).

Ref.: Nursing Procedure Manual I-A & B
Medical Staff Regulation 101 (#4)

APPENDIX E

SAMPLE SIZE CALCULATION

Sample Size Calculation

Power analysis based on ANOVA (Cohen & Cohen, 1983)

At an alpha level of 0.05, and a power level of 0.80 with an effect size of 0.40;

where: N= number of subjects per cell
u= number of groups
n_1= table value
C= number of cells

$$N= \frac{(n_1-1)(u+1)}{C} +1$$

$$N= \frac{(26-1)(1+1)}{4} +1$$

$$N= \frac{(25)(2)}{4} +1$$

$$N= 13.5$$

Therefore, for an alpha level of 0.05 and a power of 0.80 approximately 14 subjects per cell are needed. Since each cell involves the same subjects only 14 subjects in total are needed and this has been rounded up to a total of 15 subjects.

APPENDIX F

ASHWORTH SCALE FOR MEASURING SPASTICITY

Ashworth Scale for measuring spasticity

Grade	
0	no increase in tone
1	slight increase in tone giving a slight "catch" when the limb is moved in flexion or extension
2	more marked increase in tone but the limb is easily flexed or extended
3	considerable increase in tone and passive movement is difficult
4	limb is rigid in flexion or extension

APPENDIX G

STIMULATION PARAMETERS DESCRIBED IN THE LITERATURE

Stimulation parameters described in the literature:

References	Frequency (Hz)	PW (microsec)	Amplitude (mA)	Waveform
Ragnarsson et al (1988)	60	300	adjustable	M
Rodgers et al (1991)	35	300	adjustable	M
Gruner et al (1983)	30	200	adjustable	N/S
Barr et al (1989)	20	200	adjustable	N/S
Bremner et al (1992)	35	298	81	B
Hjeltnes & Lannem (1990) (3 units)	25 20 20	300 300 300	N/S	B M B
Edwards & Marsolais (1987)	25	150	20	N/S

ABBREVIATIONS USED IN APPENDIX: PW- pulse width; N/S- not stated; M- monophasic; B- biphasic

APPENDIX H

SUBJECT CHARACTERISTICS DESCRIBED IN THE LITERATURE

Subject characteristics described in the literature:

REFERENCE	N	AGE (years)	LEVEL	YRS/INJ	STRENGTH
Ragnarsson et al.(1988)	16 M 3 F	9-47	C4-T10	2-17	based on load lifted
Barr et al. (1989)	16 M 3 F	18-60	T1-T12	0.75-4.5	5 subjects > 50 N
Bajd et al. (1990)	6 M 4 F	17-40	C6-L1	0.33-9	20-100 Nm isometric
Hjeltnes and Lannem (1990)	1 M 3 F	20-36	T5-T12	0.25-5	15-100 Nm isometric 5-45 Nm 90^0/sec
Levy et al. (1990)	3 ?	26-42	T1-T6	5-9	5-70 Nm isometric
Bremner et al. (1992)	5 M 1 F	22-38	T6-T12	5-18	reported as increase or decrease
Rabischong and Ohanna (1992)	22 M 3 F	mean age 27	T2-T10	0.5-6	4.5-59 Nm isometric

ABBREVIATIONS USED IN TABLE: N- subject; YRS/INJ- years since injury; M- male; F- female; Nm- Newton meters

APPENDIX I

RAW DATA

Raw Data: Maximal Contraction at 30^0/second

N	MX	30	S1	MX	30	S2	MX	30	S3
1	13	13	13	11	12	12	10	10	11
2	11	12	10	10	11	13	8	9	10
3	102	98	100	105	107	99	86	87	93
4	22	21	21	23	23	23	31	31	32
5	49	48	48	41	43	40	44	44	44
6	38	38	37	41	42	43	60	60	59
7	12	13	11	12	12	12	9	9	9
8	6	6	6	5	5	5	5	6	6
9	43	42	43	30	30	34	44	45	43
10	24	23	23	18	19	19	22	22	21
11	45	45	45	47	46	47	54	52	49
12	74	75	76	77	75	75	76	75	75
13	29	29	27	16	16	17	29	28	27
14	41	45	42	40	40	38	36	38	37
15	28	27	28	23	23	23	34	34	34

ABBREVIATIONS USED IN APPENDIX: N- subject; MX- maximal contraction; 30- 30^0/second; S1- session 1; S2- session 2; S3- session 3

Raw Data: Maximal Contraction at 90^0/second

N	MX	90	S1	MX	90	S2	MX	90	S3
1	9	9	10	10	9	9	7	8	7
2	14	10	10	10	9	14	11	9	9
3	78	79	75	67	70	70	63	63	62
4	20	20	20	20	19	22	24	25	25
5	37	37	35	36	35	36	36	35	36
6	31	32	33	33	37	37	50	50	50
7	10	10	11	12	9	10	9	10	11
8	4	5	6	4	5	2	3	3	2
9	30	29	28	17	19	18	20	21	21
10	22	22	22	16	19	17	20	20	20
11	33	34	33	34	35	34	32	33	33
12	57	57	57	52	50	51	56	53	52
13	28	29	26	15	15	15	28	28	27
14	39	34	32	34	34	34	25	24	24
15	18	20	18	15	14	15	19	20	20

ABBREVIATIONS USED IN APPENDIX: N- subject; MX- maximal contraction; 90- 90^0/second; S1- session 1; S2- session 2; S3- session 3

Raw Data: Submaximal Contraction at 30^0/second

N	SB	30	S1	SB	30	S2	SB	30	S3
1	7	7	7	6	5	5	6	5	5
2	5	6	4	5	4	5	3	3	3
3	59	57	57	53	50	50	50	52	51
4	13	12	13	13	13	14	19	19	19
5	35	36	35	30	30	30	33	34	32
6	15	15	14	15	15	15	18	19	21
7	9	8	8	9	9	9	7	7	7
8	3	3	3	2	2	3	3	4	4
9	26	25	25	15	15	14	23	23	22
10	14	13	13	9	11	9	11	11	10
11	29	27	28	28	30	28	38	38	36
12	57	56	56	56	56	55	49	50	49
13	13	13	13	7	8	7	14	14	13
14	29	28	28	28	25	26	25	24	24
15	11	11	11	7	7	7	12	11	12

ABBREVIATIONS USED IN APPENDIX: N- subject; SB- submaximal contraction; 30- 30^0/second; S1- session 1; S2- session 2; S3- session 3

Raw Data: Submaximal Contraction at 90^0/second

N	SB	90	S1	SB	90	S2	SB	90	S3
1	7	8	6	7	5	6	4	4	5
2	5	7	4	7	7	7	3	4	3
3	45	47	48	36	35	35	35	35	35
4	10	11	12	10	11	13	16	16	16
5	27	27	21	27	27	27	26	26	27
6	14	14	14	15	15	15	19	15	15
7	8	7	5	9	7	9	8	7	8
8	2	2	4	2	2	4	2	4	2
9	16	15	15	4	6	6	11	13	14
10	14	14	13	8	8	8	13	13	13
11	24	23	24	21	22	23	29	28	29
12	38	41	40	36	38	35	35	36	34
13	18	18	18	6	5	6	17	17	15
14	24	25	25	20	19	21	24	24	24
15	8	8	8	4	5	6	7	7	7

ABBREVIATIONS USED IN APPENDIX: N- subject; SB- submaximal contraction; 90- 90^0/second; S1- session 1; S2- session 2; S3- session 3

APPENDIX J

Z-TEST CALCULATION

Z-test calculation

$$Z = \frac{Z_{r1} - Z_{r2}}{SD_Z}$$

where;

Z_{r1} = z score for correlation coefficient 1

Z_{r2} = z score for correlation coefficient 2

SD_Z = square root of $\frac{1}{(N_1 - 1)} + \frac{1}{(N_2 - 1)}$

N = number of subjects